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08/989,881	12/12/1997	JEN SHEEN	08472/716002	9398
21559	7590	07/14/2004	EXAMINER COLLINS, CYNTHIA E	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			ART UNIT 1638	PAPER NUMBER
DATE MAILED: 07/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/989,881

Applicant(s)

SHEEN, JEN

Examiner

Cynthia Collins

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 24-26, 36-46, 49 and 50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 24-26, 36-46 and 49-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The amendment filed April 9, 2004, has been entered.

Claims 1, 24 and 36 are currently amended.

Claims 8-23, 27-35 and 47-48 are cancelled.

Claims 1-7, 24-26, 36-46 and 49-50 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

Claims 1-7, 24-26, 36-39 and 41-46 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed October 6, 2003.

Applicant's arguments filed April 9, 2004, have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn in light of the amendment of claims 1, 24 and 36 to recite that the encoded calcium-dependent protein kinase polypeptide includes a PK domain "having a sequence that is at least 90% identical to SEQ ID NO:2". Applicant points out that the claimed methods and compositions include DNA molecules that encode proteins that are distinguished from other proteins by both the structural characteristic of

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having at least 90% sequence identity to SEQ ID NO:2, and by the specific functional characteristic of increasing tolerance to an environmental stress in a plant (reply pages 9-10).

Applicant argues that because the clear distinguishing characteristics that are shared by the DNA molecules recited in applicant's claims are disclosed in applicant's specification, and because the claims, as amended, are in accordance with the PTO's applicable standard for determining compliance with the written description requirement, this rejection should be withdrawn (reply page 10).

The Examiner acknowledges that the language of the claims as amended is in accordance with the PTO's applicable standard for determining compliance with the written description requirement, in that the amended claims recite both a particular structural characteristic (having at least 90% sequence identity to SEQ ID NO:2) and a particular functional characteristic (increasing tolerance to an environmental stress in a plant), but the Examiner disagrees with Applicant's assertion that the genus of DNA molecules recited in the claims are disclosed in Applicant's specification. The specification describes only two highly homologous calcium-dependent protein kinase sequences (ATCDPK1 and ATCDPK1a) obtained from one plant species (*Arabidopsis*) that have 96% and 100% amino acid sequence similarity to SEQ ID NO:2 and that can transactivate a stress-inducible HVA1-LUC reporter construct in a transient maize protoplast system, one of which (ATPK1) has also been shown to confer drought tolerance to transgenic *Arabidopsis* plants.

The written description rejection is maintained because Applicant has not described a representative number of species falling within the scope of the genus that encompasses DNA sequences obtained from any unspecified source that encode calcium-dependent protein kinase

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polypeptides that include a PK domain having a sequence that is at least 90% identical to SEQ ID NO:2 and that increase tolerance to any environmental stress in a plant transformed therewith, nor the structural features correlated with increasing tolerance to any environmental stress in a plant that are unique to the genus. Applicant also has not described a representative number of species falling within the scope of the genus that encompasses DNA sequences obtained from any unspecified source that encode any unspecified fragment of a calcium-dependent protein kinase polypeptide that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO:2 and that increase tolerance to any environmental stress in a plant transformed therewith, nor the structural features correlated with increasing tolerance to any environmental stress in a plant that are unique to the genus.

Claims 1-7, 24-26, 36-46 and 49-50 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing transgenic plants that are drought tolerant as a result of the overexpression of a transgene encoding the PK domain of AtCDPK1, does not reasonably provide enablement for producing transgenic plants that are tolerant to other environmental stresses, or for methods for producing transgenic plants that are tolerant to environmental stresses as a result of the overexpression of other transgenes encoding other CDPK polypeptides, for the reasons of record set forth in the office action mailed October 6, 2003.

Applicant's arguments filed April 9, 2004, have been fully considered but they are not persuasive.

As an initial matter, Applicant notes that the claims now require a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2, and that the scope of the claims is therefore limited to sequences that are highly homologous, and therefore necessarily structurally similar, to the disclosed sequence (reply page 10). Applicant argues that with the recitation of a specific level of identity in the claims to the PK domain of a CDPK shown to promote stress tolerance, no undue trial and error experimentation would be required to identify and distinguish CDPKS that increase the level of tolerance of a plant to an environmental stress from those CDPKS that do not provide such tolerance (reply page 11).

The Examiner maintains that the scope of the claims as amended is not limited to sequences that are highly homologous, but to sequences that have highly homologous PK domains. Accordingly, the sequences are necessarily structurally similar to the disclosed sequence only with respect to the PK domain. The Examiner further maintains that the requirement for a specific level of identity in the claims to the PK domain of a CDPK shown to promote stress tolerance does not obviate the need for trial and error experimentation to identify and distinguish CDPKS that increase the level of tolerance of a plant to an environmental stress from those CDPKS that do not provide such tolerance, because it is unpredictable whether any DNA obtained from any source that encodes any CDPK polypeptide or fragment that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2 would increase tolerance to any environmental stress in a plant transformed therewith, since even small changes in the amino acid structure of a protein could significantly affect the protein's function. The specification also does not provide sufficient guidance for identifying and distinguishing these DNAs, since the specification discloses only two highly homologous calcium-dependent protein

kinase sequences (ATCDPK1 and ATCDPK1a) obtained from one plant species (*Arabidopsis*), both of which can transactivate a stress-inducible HVA1-LUC reporter construct in a transient maize protoplast system, and one of which (ATPK1) has also been shown to confer drought tolerance to transgenic *Arabidopsis* plants.

With respect to environmental stresses other than drought, Applicant argues that in asserting that one wishing to practice the invention would have to proceed by trial and error experimentation, testing each particular CDPK polypeptide for its ability to protect a plant against one or more environmental stresses." the Office in essence reasons that a large amount of screening would be required in order to determine which CDPK polypeptides effectively increased a plant's tolerance to a particular environmental stress other than drought. Applicant maintains that even if this assertion were accurate, the mere fact that one skilled in the art would be required to screen a large number of different embodiments does not mean that undue experimentation is required to practice the invention. (reply page 11)

The Examiner maintains that in asserting that one wishing to practice the invention would have to proceed by trial and error experimentation, the Office did not reason that a large amount of screening would be required in order to determine which CDPK polypeptides effectively increased a plant's tolerance to a particular environmental stress other than drought. The Office reasoned that one wishing to practice the invention would have to proceed by trial and error experimentation on the basis of the unpredictability of protecting a plant against one or more environmental stresses by expressing of a substantially pure DNA encoding any CDPK polypeptide obtained from any source that includes a PK domain, and on the basis of the limited

amount of guidance provided by the specification with respect to how one skilled in the art could select from among the numerous CDPK sequences available a substantially pure DNA encoding a CDPK polypeptide that would protect a plant against an environmental stress other than drought, or against a specific array of defined multiple environmental stresses. See page 8 first paragraph and page 10 first paragraph of the office action mailed October 6, 2003.

Applicant further points to *Ex parte Chen*, 61 U.S.P.Q.2d 1025 (Bd. Pat. App. & Int. 2000), only 1% of the 1746 attempts at integrating a transgene into embryos were successful. Despite this apparently low success rate, the Board held that the claims were enabled. According to the Board, these numbers merely reflected "the need for a repetitive procedure, rather than undue experimentation by those wishing to practice the invention." *Id.* at 1028, consistent with prior Federal Circuit precedent, which has clearly established that experimentation is not undue simply because an extensive amount is required (reply page 11). Applicant argues that the present situation is, in all important aspects, indistinguishable from the operative facts in *Chen*, in which the Board held that the applicant's claims directed to transgenic organisms were enabled, despite the necessity for additional experimentation, because the methodology involved a repetitive procedure that was straightforward (reply pages 12-13).

With respect to the cited case, Applicant's reliance on *Ex parte Chen*, 61 U.S.P.Q.2d 1025 (Bd. Pat. App. & Int. 2000) is inappropriate here, as the Board of Patent Appeals and Interferences has indicated that this opinion is not binding precedent of the board. Accordingly, the board's reasoning in *Chen* is limited to the facts of that case, where the claims at issue were directed to transgenic carp containing an exogenous rainbow trout growth hormone (rtGH) gene,

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rather than to methods of increasing environmental stress tolerance in plants by transforming them with DNAs encoding CDPK polypeptides. With respect to Applicant's observation that Federal Circuit precedent has clearly established that experimentation is not undue simply because an extensive amount is required, the Examiner does not dispute this observation, but maintains that undue experimentation would be required to practice the full scope of the claimed invention because of the unpredictability of recited sequences producing the desired effect, because of the limited amount of guidance provided in the specification with respect to which sequences would produce the desired effect and which would not, and because of the limited amount of guidance provided in the specification with respect to which stress tolerances would be increased and which would not.

Applicant points also to the specification, on page 36, under the heading "Engineering Stress-Protected Transgenic Plants", which provides a detailed description of techniques as to how to obtain plants having tolerance to a variety of environmental stresses. In particular, a working example of the expression of a PK domain gene in tomato to increase the salt stress tolerance is presented. Applicant argues that based on this description in the specification, a skilled artisan, using no more than routine experimentation, could easily screen salt-tolerant plants expressing a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2, since such screening could easily be accomplished using standard techniques for generating transgenic plants.

The Examiner maintains that the instant rejection is not predicated on whether one skilled in the art of plant transgenics could transform plants and screen them for tolerance to

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environmental stresses, as transforming plants and evaluating their phenotypes are considered to be within the abilities of one skilled in this art. The instant rejection is predicated on the unpredictability of recited sequences producing increasing tolerance to any and all unspecified environmental stresses in a plant transformed therewith, the limited amount of guidance provided in the specification with respect to which sequences would increase tolerance to any and all unspecified environmental stresses in a plant transformed therewith and which would not, and the limited amount of guidance provided in the specification with respect to which of a multitude of different stress tolerances would be increased and which would not. The Examiner further notes that the working example of the expression of a PK domain gene in tomato to increase the salt stress tolerance referred to by Applicant appears to be prophetic, and suggests only that tolerance to a single type of environmental stress (salt) would be increased in tomato plants upon expression of an unspecified PK domain gene (page 36 lines 14-23). The Examiner maintains that this particular example does not provide the type of guidance needed to enable the full scope of the claimed invention, which encompasses the use of a multitude of different sequences that encode a CDPK polypeptide or fragment that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO: 2 to increase tolerance to any of a multitude of different environmental stresses in a plant transformed therewith.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 36, and claims 25-26, 37-46 and 50 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention. The amendment of claims 24 and 36 to recite “substantially pure DNA encoding a fragment of a calcium-dependent protein kinase (CDPK) polypeptide that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO:2” renders the claims indefinite because it is unclear what object “includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO:2”, the encoded fragment, or the calcium-dependent protein kinase (CDPK) polypeptide from which the fragment was obtained.

***Claim Rejections - 35 USC § 102***

Claims 36-46 remain rejected under 35 U.S.C. 102(b) as being anticipated by Urao et al. (Mol. Gen. Genet. 1994, Vol. 244, pages 331-340), for the reasons of record set forth in the office action mailed October 6, 2003.

Applicant's arguments filed April 9, 2004, have been fully considered but they are not persuasive.

Applicant argues that the rejection has been overcome by amending claims 24 and 36 to require a fragment of a calcium-dependent protein kinase (CDPK) polypeptide, which Urao fails to disclose (reply page 13).

The rejection is maintained because the amendment of claims 24 and 36 to recite “Substantially pure DNA encoding a fragment of a calcium-dependent protein kinase (CDPK) polypeptide that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO:2” does not limit the claimed DNA to DNA that encodes any particular CDPK fragment, or to DNA that encodes any particular CDPK fragment that includes a PK domain having a

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sequence that is at least 90% identical to SEQ ID NO:2. Furthermore, the use of the term “encoding” in the claims is interpreted as being open claim language, such that the rejected claims read on any DNA encoding a calcium-dependent protein kinase (CDPK) polypeptide that includes a PK domain having a sequence that is at least 90% identical to SEQ ID NO:2, such as the DNA taught by Urao et al.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Remarks***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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